

REMARKS

Claims 125, 126 and 128-144 were pending in the present application and no amendment to the claims is made. Therefore, claims 125, 126 and 128-144 will be under examination.

REJECTIONS OF CLAIMS UNDER DOUBLE PATENTING

Claims 125, 126 and 128-144 stand rejected under the judicially created doctrine of obviousness-type double patenting as being upatentable over the claims of U.S.S.No. 10/327,459, U.S.S.No. 10/387,383 (Applicants believe that it should be 10/327,383), and U.S.S.No. 10/355,575.

Applicants respectfully point out that a Terminal Disclaimer with regard to these three patent applications was filed on September 6, 2005 in the present application and its copy can be found in public PAIR. Therefore, these rejections are moot.

CLAIM REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 125, 126 and 128-144 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Office Action stated that “there is a good reason to doubt that such crystalline structure can be maintained in an aqueous environment” and that “in so far as the instant claims encompass a dosage form in a dry environment such as a tablet, there is also a good reason to doubt that the claimed product can maintain its crystalline structure under compression. Note the article by Rouhi, (Right Stuff, Chemical and Engineering News, Feb. 24, 2003, pages 32-35).” *Office Action at page 4.*

Applicants respectfully disagree with this ground of rejection because this is inconsistent with the past USPTO practice and its standard for interpreting claims on pharmaceutical compositions containing polymorphs.

The current USPTO practice is to grant patents with claims on pharmaceutical compositions containing polymorphs and by granting these patents, the USPTO would have decided that this type of claims are enabled. Applicants have briefly reviewed the USPTO patent database and found that the Patent Office has indeed granted many patents

Patent Application
Attorney Docket No. PC11724D

with claims on pharmaceutical compositions containing polyporphs. An incomplete list of such patents is shown below according to the Primary Examiner's name:

Examiner Cecilia Tsang:

- (1) granted U.S. Patent No. 6,169,108 to Sato et al. of Daiichi Pharmaceutical Co., LtD. on January 2, 2001 wherein its claim 17 is directed to a pharmaceutical composition comprising as an active ingredient the anhydrous crystal according to claim 1; and
- (2) granted U.S. Patent No. 5,869,604 to Rousseau et al. of Georgia Institute of Technology on February 9, 1999 wherein its claim 42 is directed to a biological compound crystal.

Examiner Alan L. Rotman:

- (1) granted U.S. Patent No. 6,767,913 to Lifshitz et al. of Teva Pharmaceutical Industries, Ltd. on July 27, 2004 wherein its claim 83 is directed to a pharmaceutical composition comprising clopidogrel hydrogensulfate selected from the group consisting of clopidogrel hydrogensulfate Form III, Form IV, Form V and amorphous form, and a pharmaceutically acceptable excipient.

Examiner Jose G. Dees:

- (1) granted U.S. Patent No. 6,482,417 to Leibovici et al. of Teva Pharmaceutical Industries, Ltd. On November 19, 2002 wherein its claim 1 is directed to a stable pharmaceutical formulation comprising an effective amount of high purity torsemide modification II.

Examiner Charanjit S. Aulakh:

- (1) granted U.S. Patent No. 6,465,496 to Aronhime et al. of Teva Pharmaceutical Industries, Ltd. on October 15, 2002 wherein its claim 26 is directed to a pharmaceutical composition comprising torsemide Dupont Form 2 ethanol adduct and a pharmaceutically acceptable carrier.

Examiner Fiona T. Powers:

- (1) granted U.S. Patent No. 6,605,636 to Aronhime et al. of Teva Pharmaceutical Industries, Ltd. on August 12, 2003 wherein its claim 14 is directed to a pharmaceutical composition comprising the atorvastatin hemi-calcium Form VII or a hydrate thereof of claim 2.

Examiner Elli Peselev:

- (1) granted U.S. Patent No. 6,599,884 to Avrutov et al. of Teva Pharmaceutical Industries, Ltd. on July 29, 2003 wherein its claim 14 is directed to a pharmaceutical composition comprising a therapeutically effective amount of clarithromycin Form IV; and
- (2) granted U.S. Patent No. 6,936,591 to Dumić et al. of Pliva Pharmaceutical Industry Incorporated on August 30, 2005 wherein its claim 32 is directed to a pharmaceutical composition comprising substantially pure orthorhombic isostructural pseudopolymorph of 9-deoxy-9a-aza-9a-methyl-9a-homoerythromycin A according to claim 30, and one or more pharmaceutically acceptable excipients.

By virtue of granting these patents, the USPTO has established an implied standard of interpreting this type of claims, i.e., the characteristic of the polymorph is a claim limitation and these claims do not encompass compositions where the polymorph cannot be detected and/or characterized, such as in an aqueous solution."

Under such an implied standard of interpreting claims on pharmaceutical compositions containing polymorphs, the claimed pharmaceutical dosage form would not cover dosage forms where crystalline azithromycin monohydrate hemi-ethanol solvate cannot be detected and/or characterized. Indeed, dosage form containing crystalline azithromycin monohydrate hemi-ethanol solvate can be characterized in substantially the same way as the crystalline azithromycin monohydrate hemi-ethanol solvate. As such, Applicants submit that the pending claims, when properly interpreted, are fully enabled.

Furthermore, the pending claims should be allowed because it is in the interest of the public for the Patent Office to have a consistent standard of claim interpretation and policy on enablement and patentable subject matter as well as treating all applicants equally. Therefore, Applicants believe that this ground of rejection is moot and its withdrawal is respectfully requested.

With regard to Rouhi, Applicants believe that it is not a proper reference to support this ground of rejection because it deals with the problem of stabilizing polymorphs which the author defined as crystals having identical chemical composition. Applicants believe that it is clear from the specification and the cited references, there is

only one known polymorph for azithromycin monohydrate hemi-ethanol solvate under the definition of Rouhi, i.e., having azithromycin:water:ethanol ratio of 1:1:0.5. The Office Action did not provide any evidence that a second polymorph for azithromycin monohydrate hemi-ethanol solvate can exist, let alone talking about conversion between the first polymorph and the second polymorph of azithromycin monohydrate hemi-ethanol solvate in a solid dosage form. In addition, the Office Action did not provide any evidence that the claimed azithromycin monohydrate hemi-ethanolate can convert to a different polymorph having the same azithromycin:water:ethanol ratio of 1:1:0.5 in a solid dosage form.

Even assuming that Rouhi can be used as a reference to support this ground of rejection and further assuming that there is more than one polymorph for azithromycin monohydrate hemi-ethanol solvate, Applicants would still have provided enabling disclosure to the claimed pharmaceutical dosage form because the claimed pharmaceutical dosage form containing azithromycin monohydrate hemi-ethanol solvate would include all azithromycin polymorphs having an azithromycin:water:ethanol ratio of 1:1:0.5. The conversion between various polymorphs as defined by Rouhi, even if it exists, does not defeat the enabling disclosure of the claimed pharmaceutical dosage form. Therefore, Applicants have provided enabling disclosure to all pending claims and that the Examiner has not met her burden to establish a reasonable basis to question the enablement provided for the claimed invention. *see M.P.E.P. §2164.04 and In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)* and there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure. *see 439 F.2d at 224, 169 USPQ at 370.*

CLAIM REJECTION UNDER 35 U.S.C. §102(b) AND/OR §103(a)

Claims 125, 126 and 128-144 stand rejected under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §102(b) as obvious over Bright, U.S. Patent No. 4,474,768 (hereinafter “Bright”).

Applicants respectfully disagree with this ground of rejection. On August 31, 2005, Applicants submitted a copy of Dr. Hangac’s declaration showing that Bright does

Patent Application
Attorney Docket No. PC11724D

not produce substantially pure azithromycin. In addition, as stated in Applicants' response to enablement rejection, the pending claims, when properly interpreted under the current USPTO standard, would not cover pharmaceutical compositions containing azithromycin monohydrate hemi-ethanol solvate where azithromycin monohydrate hemi-ethanol solvate cannot be detected and/or characterized. Therefore, Bright does not anticipate any of the pending claims, nor does Bright render these claims obvious. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

CONCLUSION

In view of the remarks, further and favorable considerations of the presently pending claims are respectfully requested.

It is believed that no fee, other than the \$120 of one-month extension of time fee, is required in connection with the present Response. However, if any fees are required, the Commissioner is authorized to charge such fees to our Deposit Account No. 16-1445.

Respectfully submitted,

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